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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/857,069 | 05/31/2001 | Joseph Hamburger | 01/22115 | 9244 |

7590 09/17/2004

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EXAMINER

CHEN, SHIN LIN

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/857,069

Applicant(s)

HAMBURGER ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 102(b).
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 53-63 and 65-69.Claim(s) withdrawn from consideration: None.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the present invention refers to multicellular eukaryotic diploid parasite and *C. elegans* is not a parasite (amendment, p. 5). This is not found persuasive because of the reasons of record. *C. elegans* is a rhabditid nematode and many nematodes are parasites. For example, the animal parasitic Strongylida including human hookworms *Ancylostoma* and *Necator*, are within Rhabditida. Therefore, it would have been obvious for one of ordinary skill in the art to use biolistic bombardment method as taught by Rushforth to obtain stable transformation of a diploid parasite, such as schistosome, because *C. elegans* and many parasitic nematodes are closely related and schistosome is a parasite. Applicants argue that the method of Rushforth was not accepted or adapted in the art because the Miller reference teaches using microinjection and was published 6 years after the Rushforth reference (amendment, bridging p. 5-6). This is not found persuasive because although Miller reference teaches using microinjection and was published 6 years after Rushforth reference, it does not mean that biolistic bombardment method would not work or would not be obvious for one of ordinary skill in the art at the time of the invention. It could be that microinjection method was a more common method for making a transgenic animal than biolistic bombardment during that period of time. Although the particle-mediated transformation efficiency may be low, however, the teachings of Rushforth and Miller would make it obvious for one of ordinary skill in the art at the time of the invention to practice the claimed invention with reasonable expectation of success for the reason discussed in the preceding Official action mailed 3-25-04 and the reasons set forth above. Applicants argue that Rushforth admits that the transforming DNA is likely to be extrachromosomal and the phrase "heritable transformants" used by Rushforth merely refers to extrachromosomal transformants (amendment, p. 6). This is not found persuasive because Rushforth discloses that "[A]lthough the frequency is low, the process is fast and simple, and we routinely recover hundreds of transformants in a single experiment. About 10-30% of transformants are heritable for many generations...Most of the heritable transformants continue to segregate uncoordinated offspring...the transforming DNA is likely to be extrachromosomal." Therefore, there are hundreds of transformants produced in a single experiment and although most of the heritable transformants could have extrachromosomal transgene, there still are some heritable transformants that are stable transformants. Further, Rushforth indicates the biolistic bombardment method is a fast and simple process and suggests that further improvements in this transformation procedure will yield increased efficiencies. therefore, Rushforth provides motivation for one of ordinary skill to use biolistic bombardment method to make transgenic animal. Applicants argue that the microinjection method taught by Miller is ineffective and therefore Miller fails to teach one of ordinary skill in the art how to transform schistosomes and present invention has distinct advantages over the method taught by Miller as explained in detailed and carefully designed experimental set-up in the Examples (amendment, p. 6). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-25-04 and the reasons set forth above. Microinjection method for making a transgenic animal was well known in the art at the time of the invention and one of ordinary skill in the art at the time of the invention would be able to make a transgenic schistosome via microinjection according to the teachings of Miller with reasonable expectation of success. Further, the claim do not specify what specific experimental set-up and conditions that would make the claimed invention preferable or distinguishable from the method known in the prior art. Thus, the claims remain rejected under 35 U.S.C. 103(a).